ORGANIZATION POLICY

I. POLICY TITLE: 340B Drug Purchasing and Compliance

II. POLICY NUMBER: 1232

III. **Purpose:**

A. To define a systematic approach to ensure adherence to the rules and regulations of the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program (340B Program).

B. To provide guidelines and procedures for managing 340B drug purchasing and compliance at Onslow Memorial Hospital.

IV. **Policy:**

A. Onslow Memorial Hospital participates in the 340B Program and complies with guidelines and regulations to insure that 340B drug products are purchased only for eligible facilities and patients.

B. Staff follow the processes identified within this policy which address the four key compliance elements for administration of the 340B Program:

1. Covered entity / patient eligibility compliance.

2. Anti-diversion inventory controls / compliance.

3. Medicaid pricing compliance.

4. State Medicaid cost rebate verification (compliance with "double-dipping" prohibition).

V. **Definitions:**

A. **340B Drug Pricing Program (340B Program)** – A drug pricing program that resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to "covered entities" including disproportionate share hospitals and sole community hospitals.

B. **Authorizing Official** – The Onslow Memorial Hospital employee, officer, or director that is designated as the "Authorizing Official" in the database of the Office of Pharmacy Affairs under the 340B program.

C. **Covered Entities** - Facilities and programs eligible to purchase discounted drugs through the 340B Program.

D. **Disproportionate Share Hospitals (DSH)** - Facilities that serve a significantly disproportionate number of low-income patients.

E. **Diversion** - Covered entities are required to prevent the resale or transfer of drugs purchased at 340B prices to non- eligible patients/facilities. Failure to ensure appropriate use is considered diversion.

F. **Group Purchasing Organization (GPO)** - An organization that represents and organizes a group of hospitals to evaluate and select pharmaceutical products. Using the purchasing power of the entire group, the GPO negotiates contracts that are more favorable than a single organization could achieve.

G. **Health Resources Services Administration (HRSA)** - An agency of the U.S. Department of Health and Human Services that is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable. The primary mission of HRSA is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.

H. **Hospital Based Clinic** - A clinic that appears on a reimbursable line of the Onslow Memorial Hospital most recently filed Medicare Cost report and is thus eligible for 340B priced drugs.

I. **Medicaid Exclusion File** - Covered entities are required to designate in the application process whether 340B drugs will be utilized for Medicaid patients. HRSA maintains this information in the Medicaid Exclusion File which is available to state Medicaid programs. The purpose of this file is to exclude 340B drugs from Medicaid rebate requests. This prevents drug manufacturers from providing duplicate discounts – upfront as the 340B drug price and the later as the Medicaid rebate.

J. **Mixed Use Area** - A location that serves both outpatients and inpatients as designated by the Onslow Memorial Hospital patient registration system. These areas include but are not limited to: Emergency Room, Surgery Suites, Cath Lab, Endoscopy and Interventional Radiology.

K. **Office of Pharmacy Affairs (OPA)** - A component of the Health Resources and Services Administration Healthcare Systems Bureau which provides administration of the 340B Program, through which certain federally funded grantees and other safety net health care providers may purchase prescription medication at significantly reduced prices.

L. **Orphan Drugs** – A special status given to a drug under the Orphan Drug Act to treat a rare disease or condition upon request of a sponsor. The use of the drug to

treat the rare disease or condition must meet certain criteria contained in the Orphan Drug Act in order to be classified as an Orphan Drug.

M. **Pharmacy Buyer** – The designated staff member of Onslow Memorial Hospital who does all purchasing functions for the Department of Pharmaceutical Services with the exception of C-2 controlled drugs.

N. **Public Health Service (PHS)** – A division of the U.S. Department of Health and Human Services with the purpose of delivering public health promotion and disease prevention programs and advancing public health science. Agencies within the PHS include the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA).

O. **Prime Vendor** - The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract awarded by Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program. Apexus is responsible for securing sub-ceiling discounts on outpatient drug purchases and discounts on other pharmacy related products and services for participating entities.

P. **Rebates (as it relates to the 340B Program)** - The Federal Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for covered outpatient drugs administered by "physicians." In order to comply, states gather utilization data including National Drug Code (NDC), quantity, and unit of measure from claims submitted for physician administered drugs. Medicaid Agencies are not required to collect a rebate on 340B drugs.

Q. **Splitting Software** - Software employed, on an ongoing basis, to manage the splitting of eligible, outpatient charges from ineligible, inpatient charges in order to purchase eligible medications on the 340B contract.

VI. Competencies Required:

A. Pharmacy staff completes basic training on the 340B Program initially upon hire and competency is also verified annually. The training focuses on the compliance issues related to the transfer of drug between the two types of inventory.

B. Pharmacy Buyer with procurement responsibilities is provided comprehensive training on the 340B Program and the compliance requirements of this program. This training is completed by the Director of Pharmacy initially upon hire and competency is also verified annually. Staff complete basic training on the 340B and Prime Vendor Programs and attend 340B University every 2 years.

VII. Covered Entity and Sub-division Eligibility Compliance:

A. Onslow Memorial Hospital is eligible to participate in the 340B Program by meeting the following criteria for inclusion:

1. Onslow Memorial Hospital is a sole community hospital that is owned and operated by a unit of State or local government and

2. Is a Disproportionate Share Hospital (DSH) maintaining the DSH percentage required by federal law to participate in the 340B Program as a Sole Community Hospital.

B. Onslow Memorial Hospital's outpatient sites bill as provider-based entities and appear on the most recently filed Medicare cost report, as a reimbursable clinic, to be eligible for 340B purchasing program. These sites must be registered as child sites of Onslow Memorial Hospital with OPA.

C. Onslow Memorial Hospital complies with the process to include a new 340B Site/Facility in the 340B Drug Purchasing Program:

1. Onslow Memorial Hospital, assisted by the Department of Finance Third Party Reimbursement Manager, evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program and documents its findings in written correspondence to the Department of Pharmaceutical Services. The Onslow Memorial Hospital Department of Finance and Pharmaceutical Services validates that the site/facility appears on the most recently filed Medicare Cost Report as reimbursable before utilizing 340B purchased drugs at the site.

2. Facility/area eligibility is validated annually with collaboration of Legal, Finance and Pharmacy. This is accomplished at the time the Medicare Cost Report is finalized and filed. If any new eligible sites have been added, the patient medication utilization data are added to the 340B eligible drug purchases. If any previous eligible sites are removed from the Medicare cost report the patient medication utilization data is removed from 340B eligible purchases.

3. The registration of the Onslow Memorial Hospital and its child sites on the HRSA/OPA site is reviewed annually in conjunction with the facility/area eligibility review. All data in the registration file is reviewed for accuracy and compliance with guidelines for registration.

D. Process to enroll a new entity sub-division name for locations not included by existing Covered Entities:

1. The Director of Pharmacy in collaboration with the Department of Finance Third Party Reimbursement Manager is responsible for completing the

340B Participant Change Form (found on the OPA web site) to submit a new entity sub-division.

2. The pharmacy then forwards the completed 340B Participant Change Form to the Chief Financial Officer for submission to OPA.

3. All information on the 340B Participant Change Form should match identically to the DEA and State Board registrations.

E. Procurement Compliance: Establishing a Prime Vendor 340B Purchasing Account:

1. Once an entity sub-division is established and the 340B eligibility of its patients is determined, a pharmacy purchasing account is established through the Prime Vendor.

2. If 340B-eligible patients are to be treated, the account is designated as a 'PHS' account and appropriate PHS contract pricing from the Prime Vendor is loaded.

3. Eligibility of the account is verified by the Prime Vendor through OPA (see references for a listing of the Onslow Memorial Hospital prime vendor accounts).

F. Procurement Compliance: Establishing a Direct Purchase 340B Purchasing Account:

1. If it is determined a 340B-eligible medication must be purchased that is not available through the Prime Vendor, the pharmacy purchasing agent establishes a PHS account with the direct vendor. While some direct vendors use a single account for both non-PHS and PHS purchases, Onslow Memorial Hospital requests a separate PHS account when possible for easier audit and management capabilities. Eligibility in the 340B Program is verified by the direct vendor prior to the account being established.

2. The direct purchase accounts established for 340B can be found in the Department of Pharmaceutical Services Direct Purchasing database.

G. Procurement Compliance: Purchasing Drugs on 340B Accounts:

1. Prime Vendor purchases:

a. Separate Prime Vendor accounts are maintained for the purchase of 340B medications.

b. Each account is populated with the 340B contract load and is designated as a 340B account in the account name.

c. The contract load is performed each quarter with new purchase prices provided by HRSA/OPA through the Prime Vendor.

d. 340B purchases from the Prime Vender are purchased on a 340B specific account.

e. These purchases are made on an 11 digit NDC to NDC basis.

f. If changes in purchasing are dictated by availability, changes are noted in the accumulator. 9 digit NDC match is attempted, if 11 digit match is not possible.

2. Direct Purchases:

a. Drugs not available from the prime vendor are purchased from the manufacturer using a direct account.

b. Separate 340B accounts are maintained with each manufacturer to purchase 340B drugs.

c. The 340B designation and contract price is maintained in the Direct Purchase database.

d. These purchases are made on an 11 digit NDC to NDC basis.

e. If changes in purchasing are dictated by availability, changes are noted in the accumulator. 10 digit NDC match is attempted, if 11 digit match is not possible.

H. Crediting and Rebilling:

1. Credits of purchased medications and subsequent rebills are processed in the event a 340B account is utilized for a medication purchase that should have been purchased on a non-340B purchasing account.

2. Credits of purchased goods and subsequent rebills are processed in the event a non-340B purchasing account is utilized to purchase drugs that are eligible for 340B purchase. Onslow Memorial Hospital petitions the manufacturer, via the distributor, to credit the non-340B purchasing account and rebill the 340B account. The manufacturer may or may not accept Onslow Memorial Hospital's request.

VIII. Patient/Prescriber Eligibility Compliance:

Eligible medication orders or prescriptions are filled with 340B-purchased inventory for qualified patients.

A. An individual is considered a patient of a covered entity if:

1. The covered entity has established a relationship with the individual, which includes maintaining records of the individual's health care.

2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the individual's care remains with the covered entity.

B. An individual is not considered a "patient" if the sole healthcare service rendered is the dispensing of a drug.

C. An Onslow Memorial Hospital patient is considered qualified for 340B medications in the following cases:

1. The patient is treated in a hospital-based clinic that appears as reimbursable on the most recently filed Medicare cost report, and has an eligible medication order for physician administered drugs or an eligible prescription for pharmacy dispensed drugs (including prescriptions on discharge), written by a prescriber employed by, under contract or referral relationship with Onslow Memorial Hospital.

2. The patient is treated in a hospital-based mixed use area, and is classified as an outpatient by the Onslow Memorial Hospital Patient Registration System at the time of dispensing of the medication, and has an eligible medication order or prescription (per 340B Patient Definition).

D. Medications dispensed to an inpatient are not eligible for 340B discounted drugs.

IX. Anti-Diversion Inventory Controls / Compliance:

A. 340B drugs are not resold or transferred to any party other than a patient as previously defined (unless the party is a bona fide agent of either the hospital or patient)

B. Virtual Inventory:

1. Virtual inventories are utilized to simplify the ordering, dispensing and inventory process which facilitates compliance with 340B Program regulations. The virtual inventory is maintained with splitting software

that captures 340B eligible drug utilization in accumulators. The accumulators maintain the quantities of drug that can be ordered on the 340B contract.

2. Inventory in the inpatient pharmacies, outpatient retail pharmacies, and the Oncology Pharmacy is managed utilizing 340B splitting software.

3. 340B purchases are processed by procurement staff with specialized training.

4. Dispensing staff are not required to make any determinations regarding the stock to be utilized when dispensing.

5. Eligible dispenses are accumulated in virtual 340B accumulators.

6. When a shipping unit of the drug is achieved in the accumulator, the splitting software generates a 340B order for the drug.

7. The accumulator is automatically adjusted when the order is generated.

X. Medicaid Pricing (State of North Carolina):

A. Outpatient prescriptions filled at Onslow Memorial Hospital outpatient pharmacies are <u>not</u> billed to Medicaid at the 340B cost.

B. Onslow Memorial Hospital's Medicaid Program serves its members through a managed care model. Onslow Memorial Hospital contracts with the Managed Care companies who are at risk for physician-administered drugs, and bills according to the contract terms.

XI. Compliance with Duplicate Discount Prohibition

A. State Medicaid agencies are required to exclude claims for 340B purchased drugs from Medicaid rebate requests to prevent subjecting drug manufacturers to duplicate discounts (i.e., selling 340B purchased drugs to covered entities at the discounted ceiling prices and providing Medicaid rebates on the same drugs).

B. As part of the covered entity registration, Onslow Memorial Hospital will decide whether to use 340B purchased drugs for Medicaid patients. This is decision is made by answering on the HRSA-OPA website the question: Will you bill Medicaid for drugs purchased at 340B price?

C. Answering YES to this question, places the 340B purchases on the Medicaid exclusion list. Answering NO to this question eliminates drugs purchased at 340B prices from the Medicaid exclusion file.

D. The Medicaid exclusion list is provided to the State via HRSA-OPA and maintained as part of the Medicaid Exclusion file on the HRSA web site (see references). Onslow Memorial Hospital documentation of the Medicaid exclusion for each covered entity can be found on this website.

E. In addition, the Director of Pharmacy has contacted the state Medicaid Pharmacy Program Director, and has written documentation that the state is not seeking a Medicaid rebate on Onslow Memorial Hospital 340B drugs (i.e., physician administered, contract pharmacy, managed care, etc.)

XII. 340B Program Oversight:

A. Oversight of the 340B Program is the responsibility of the Authorizing Official for Onslow Memorial Hospital as designated by the 340B Program. Additional oversight, as designated by the Authorizing Official, and performance of the responsibilities stated in this policy for the 340B Program are the responsibility of the 340B Leadership Group comprised of the following individuals:

1. Director of Pharmacy/Oncology
2. Pharmacy Buyer
3. Department of Finance – Chief Financial Officer or designee
4. Legal Office – Senior Associate General Counsel
5. Hospital Administration – Senior VP Nursing and Clinical Services or designee

B. The 340B Leadership Group has the following responsibilities:

1. Setting the general direction and policy for 340B drug purchasing and compliance.
2. Establishing an audit plan for audits conducted by the Department of Pharmaceutical Services in collaboration with the Department of Finance as well as by an external consulting group. The external audit plan is conducted annually as defined by OPA guidelines. The current audit plan is attached as an Appendix to this policy.
3. Reviewing reports, trends, and audit results.
4. Maintaining information on current best practices by sending key Onslow Memorial Hospital personnel to related conferences and/or training programs.
5. Providing compliance and oversight direction.

6. Providing appropriate resources.

7. Determining needed modifications or expansion.

8. Correcting and/or reporting deficiencies within expected timeframes.

9. Communication to hospital leadership of potential changes/trends to the 340B program that will impact the institution.

C. Discrepancies are immediately corrected and reported to the 340B Leadership Group. Any significant discrepancies are documented, corrected, and discussed with the 340B Leadership Group within two weeks (10 business days).

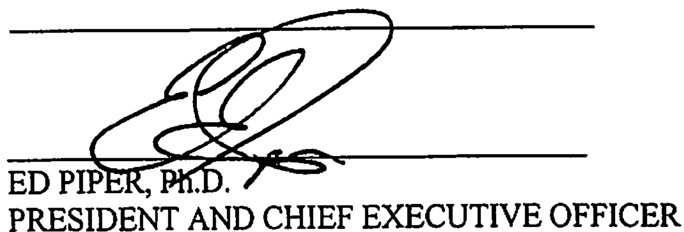
D. 340B Program related records and transactions are maintained for a period of seven (7) years in a readily retrievable and auditable format.

EFFECTIVE DATE: January 14, 2014

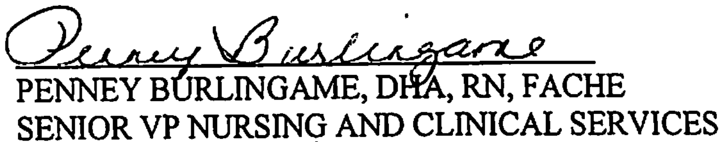
REVIEW DATE: ______________________

REVISION DATE: ______________________

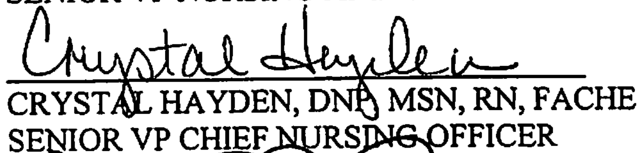
AUTHORIZED BY:



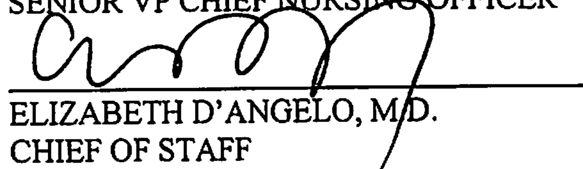
ED PIPER, Ph.D.
PRESIDENT AND CHIEF EXECUTIVE OFFICER



PENNEY BURLINGAME, DHA, RN, FACHE
SENIOR VP NURSING AND CLINICAL SERVICES



CRYSTAL HAYDEN, DNP, MSN, RN, FACHE
SENIOR VP CHIEF NURSING OFFICER



ELIZABETH D'ANGELO, M.D.
CHIEF OF STAFF

Appendix – Audit Plan

Audit Tool – Frequency	Method
OPA Website Enrollment Review – **Annual**	Confirm presence of all covered entities and accuracy of information; verify contact information including phone and e-mail information, Medicaid exclusion information and ship to/bill to information. This must include signoff by finance and legal. www.opanet.hrsa.gov/opa/CESearch.aspx
Purchasing Volume Analysis - **Monthly**	Purchasing volume for each account is reviewed at a high level to ensure purchases have been transacted on the correct account. Significant changes in purchase volume are also reviewed for appropriateness. Any variances are corrected, using credit and rebill if necessary, and documented on the 340B Audit Report.
Eligible patient review for clinics & mixed use areas - **Monthly**	Review 25 patients from mixed use areas which the splitting software designated for 340B drug purchase. Check status in * and ** to ensure patient status was Outpatient and eligible for 340B purchase. Any variances are corrected and documented on the 340B Audit Report.
Eligible drug review - **Monthly**	Review 340B purchases for drugs which are primarily utilized for inpatient use. Select 25 drugs and review to ensure that these were utilized for patients in outpatient status. Any variances are corrected and documented on the 340B Audit Report.
Accuracy of NDCs in the accumulator - **Monthly**	Review top 25 drugs in the accumulator to validate that this is the preferred product for purchase in [DISTRIBUTOR]'S software.
Review of Charges vs Purchases (every six months)	For 5 selected drugs, review 340B eligible patient charges to validate the 340B purchases for the same time period.
Physician database for Retail Pharmacies - **Monthly**	Perform a monthly assessment of the accuracy of the prescriber database to ensure proper designation. Any variances are corrected and documented on the 340B Audit Report.
Prescription transaction validation - **Daily**	Verify that the number of prescriptions filled matches the number of transactions that cross into prescription splitting software. Any variances are corrected and documented on the 340B Audit Report.
Compare prescription drugs accumulated against drugs purchased - **Monthly**	For 5 selected drugs, verify that the correct quantity is purchased on the 340B accounts based on the quantity that was processed in the accumulator.

* Onslow Memorial Hospital's patient registration system which processes admissions, discharges and transfers.

**Onslow Memorial Hospital's inpatient and clinic pharmacy information system.